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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/900,963

07/10/2001

Claudine Guerin-Marchand

1010830-000118

8667

21839 7590 06/19/2007
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POST OFFICE BOX 1404
ALEXANDRIA, VA 22313-1404

EXAMINER

LUCAS, ZACHARIAH

ART UNIT

PAPER NUMBER

1648

MAIL DATE

DELIVERY MODE

06/19/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/900,963	Applicant(s) GUERIN-MARCHAND ET AL.	
	Examiner Zachariah Lucas	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 May 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 28-38 is/are pending in the application.
- 4a) Of the above claim(s) 28-30,34 and 36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 31-33,35,37 and 38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 September 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 28-38 are pending in the application.
2. In the prior action, mailed on October 16, 2006, claims 27-37 were pending in the application; with claims 28-30, 34, and 36 withdrawn from consideration; and claims 27, 31-33, 35, and 37 under consideration and rejected.

In the Response of January 16, 2006, claim 27 was cancelled; claims 31-33, 35, and 37 were amended; and claim 38 was added.

3. Claims 31-33, 35, 37, and 38 are under consideration.
4. Because this action raises a new ground of rejection, it is made Non-Final.

Specification

5. **(Prior Objection- Maintained in part)** The substitute specification filed March 8, 2007 has been entered.

However, the portion of the objection relating to the amendments to the sequences in Figures 1 and 3 is maintained. The specification is objected for comprising new matter.

With respect to Figure 1, the Applicant asserts that support may be found on page 9, paragraph 5 of the specification. However, there does not appear to be anything on this page relating to SEQ ID NO: 31 (the sequence of Figure 1) on page 9, either in the specification as filed, nor in the substitute specification of March 7, 2007.

With respect to the amendment to Figure 3, the Applicant asserts that this Figure no longer has the modification to E. This argument is not found persuasive. The amendment of

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September 2006 includes this modification. The substitute specification that does not include such modifications of January 2007 was not entered. Moreover, it is noted that the drawings in that substitute specification were not compliant with the amendment practice under 37 CFR 1.121 as they do not show all the changes made to the drawings compared to the September 2006 versions of the drawings, including both the amendments to the sequences, and the amendments to the Figures to insert the sequence identifiers.

The objection is therefore maintained.

6. **(Prior Objection- Withdrawn)** In the prior action, the title of the application was objected to as not descriptive. In view of the amendment thereto, the objection is withdrawn.
7. **(New Objection)** It is requested that the Applicant amend the application to insert the heading "Brief Description of the Drawings" on page 4, line 8 of the specification.

Claim Objections

8. **(Prior Objection- Withdrawn)** Claim 31 was objected to because of the following informalities: this claim refers to a DNA encoding the amino acid sequence of Figure 7. In view of the amendment of the claim, the objection is withdrawn.

9. **(New Objection)** Claims 31, 32, and 33 are objected to because of the following informalities: the parenthesis around the sequence identification numbers should be deleted. Appropriate correction is required.

Claim Rejections - 35 USC § 101

10. **(Prior Rejection- Withdrawn)** Claims 27, 31, 32, 35, and 37 were rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. In view of the amendments to the claims, the rejection is withdrawn.

Claim Rejections - 35 USC § 112

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. **(Prior Rejection- Maintained)** Claims 31-33 and 37 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention because it is not clear what the use of the parenthetical marks around the sequence identifiers is intended to indicate. Applicant indicates that the parenthetical marks have been deleted. However, the parenthetical marks of claim 32 are marked with underlines, not with strikethroughs, and the parenthesis in claims 31 and 33 are not marked at all, in the amendment of May 29, 2007. Thus, the amendment does not use the appropriate marks to show deletion of the marks from the claims. The rejection is therefore maintained, and extended to new dependent claim 38.

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13. **(Prior Rejection- Withdrawn)** Claims 32, 33, and 37 were rejected under 35

U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Each of these claims read on a DNA encoding the first 153 amino acids of SEQ ID NO: 37, where SEQ ID NO: 37 is a DNA sequence. In view of the amendment of the claims, the rejection is withdrawn.

14. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

15. **(Prior Rejection- Maintained)** Claims 27, 32, 35, and 37 are rejected under 35

U.S.C. 112, first paragraph, as failing to comply with the written description requirement with respect to claim language “an epitope portion thereof” of the first 153 residues of SEQ ID NO: 38. Claim 27 has been cancelled from the application. The rejection is therefore withdrawn from this claim. New claim 38 has been added to the application, which claim also reads on B-cell epitopes of the liver stage antigen. The rejection is maintained against claims 32, 35, and 37, and extended to new claim 38.

The Applicant traverses this rejection on the basis that the specification provides the sequence of SEQ ID NO: 38, and teaches how to identify epitopes in a sequence. This argument is not found persuasive. The application does not disclose any examples of a specific T-cell epitope in the sequence. Moreover, the courts have determined that provision of a method for the identification of a compound does not demonstrate possession of compounds that may be so identified. See e.g., *University of Rochester v. G.D. Searle & Co.*, 69 U.S.P.Q.2d 1886, at 1895

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(CAFC 2004). The fact that the Applicant has demonstrated that such epitopes are present in clone DG536 does not demonstrate possession of the epitopes themselves because the application provides no non-functional identification for the epitopes. Applicant's arguments are therefore not found persuasive for the reasons above, and the reasons of record.

Claim Rejections - 35 USC § 102

16. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

17. **(Prior Rejection- Maintained)** Claims 27, 32, and 35 were rejected under 35 U.S.C. 102(b) as being anticipated by Guerin-Marchand et al. (Nature 329: 164-67- of record in the February 2002 IDS). Claim 27 has been cancelled from the application. Claim 35 has been amended to depend from claim 31. The rejection is therefore withdrawn from these claims. However, the rejection is extended to new claim 38, which describes similar subject matter to previously rejected claim 35 except that the new claim depends from claim 32. The rejection is therefore maintained against claims 32 and 38.

The present claims read on any DNA sequence encoding an epitope effective portion of residues 1-513 of SEQ ID NO: 38, and a B-cell epitope of the liver stage protein. As was described in the prior action, the sequence of Figure 4 of the reference provides a sequence comprising a T-cell epitope found within residues 1-153 is present (the sequence

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KLQEQQSDL), and a liver-stage B-cell epitope. Applicant's arguments with respect to the 17 amino acid repeat sequence is not found persuasive because the present claims do not exclude the presence of additional sequences to the indicated T and B cell epitopes.

The rejection is therefore maintained for the reasons above, and the reasons of record.

18. **(Prior Rejection- Maintained)** Claims 27, 32, and 35 were rejected under 35 U.S.C. 102(b) as being anticipated by U.S. 5,602,031. The rejection is withdrawn from claims 27 and 35, and is extended to new claim 38.

Applicant asserts that claim 32 reads on a sequence that "consists of the first 153 amino acids of SEQ ID NO: 38." This is not an accurate description of the claims. The claim reads on a DNA that encodes a polypeptide that "has" an amino acid sequence consisting of the first 153 residues of SEQ ID NO: 38 or an epitope effective portion thereof. A claim excluding other sequences would read on a DNA encoding a polypeptide consisting of SEQ ID NO: 38 of an epitope thereof. Because the present claims read on a DNA wherein the polypeptide "has" such a sequence, it may additionally include other sequences. The Applicant's arguments are not found persuasive for the reasons above, for the reasons indicated above with respect to the rejection over Guerin-Marchand, and for the reasons of record.

19. **(Prior Rejection- Maintained)** Claims 27 and 32 were rejected under 35 U.S.C. 102(b) as being anticipated by WO 88/05785 (of record in the February 2002 IDS- a translation of the disclosure of which is found in U.S. 5,599,542). The rejection is withdrawn from claim 27, which has been cancelled.

The rejection is maintained over claim 32 for the reasons of record. Applicant's argument in traversal is not understood. It appears that the Applicant traverses the rejection for the same reasons as asserted with respect to Guerin-Marchand above. This argument is not found persuasive for the reasons above.

20. **(Prior Rejection- Withdrawn)** Claims 27 and 32 were rejected under 35 U.S.C. 102(a) as being anticipated by Zhu et al. (Mol Biochem Parasitol 48:223-26). In view of the submission of the certified translation of the foreign priority application, the rejection is withdrawn.

Claim Rejections - 35 USC § 103

21. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

22. **(Prior Rejection- Maintained)** Claims 27, 32, and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 88/05785, as applied against claims 27 and 32 above. Claim 27 has been cancelled from the application. The rejection is therefore withdrawn from this claim, but maintained against claims 32 and 37.

The Applicant traverses this rejection on the basis that the reference does disclose the sequence as set forth in claim 32. This argument is not found persuasive. The applicant appears to be asserting that claim 32 is limited to DNA sequences encoding a fragment of the first 153

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residues of SEQ ID NO: 38. This argument is not found persuasive for the reasons indicated with respect to the rejection over U.S. 5,602,031 above.

The Applicant further asserts that the reference provides no motivation or incentive for the modification of the sequences set forth in the reference. However, the reference itself suggests the modification of the sequence to make the claimed fusion proteins. See e.g., page 5 lines 10-25 (corresponding to the paragraphing spanning columns 2-3 of U.S. patent 5,599,542). The Applicant's argument that there is no motivation to modify the sequences is therefore not found persuasive.

The rejection is therefore maintained.

23. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Double Patenting

24. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application

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claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

25. **(Prior Rejection- Restated and Maintained)** Claims 27 and 35 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 5,602,031. Claim 27 has been cancelled from the application. Claim 35 has been amended to read on a DNA Encoding the polypeptide of claim 31 (i.e. SEQ ID NO: 38). However, the rejection is restated as a rejection of claims 32 and 38 over claim over claim 2 of the patent. This is because the patent claims DNAs encoding peptides disclosed as inducing antibodies against the liver stage antigen (therefore comprising B-cell epitopes), and because some of the claimed DNAs also encode the LSA T-cell epitope KLQEQQSDL. The claim therefore anticipates claims 32 and 35. Thus, an obviousness type double patenting rejection is appropriate.

26. **(New Rejection)** Claims 32, 37, and 38 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 2 of U.S. Patent No. 5,602,031 in view of Marchand et al., WO 88/05785. The claims of the present application and the patent have been described previously. The claims of the patent do not require, as required by

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claim 37, that the encoded polypeptide is linked to one or several amino acids of a peptide other than LSA. However, the Marchand reference provides similar teachings to the patent. This reference teaches that the anti-LSA immunogenic peptides may be fused to other sequences, such as carrier proteins or other antigens. Page 5, lines 10-25 (corresponding to paragraph spanning columns 2-3 in U.S. 5,599,542). From these teachings, it would have been obvious to those of ordinary skill in the art to make similar fusions with the peptide of the '031 patent. The combined teachings of the patented claim and the Marchand reference therefore render the present claims obvious.

Conclusion

27. No claims are allowed.

28. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Z. Lucas/

Patent Examiner, AU 1648